NATIONAL WOMEN'S HEALTH NETWORK

CDER/FDA Stakeholders Meeting

Comments of Cynthia A. Pearson, Executive Director National Women's Health Network

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The only national public-interest membership organization devoted solely to women and health

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Good afternoon. My name is Cynthia Pearson, Executive Director of the National Women's Health Network, a national non-profit women's health advocacy organization. The Network is supported by 12,000 individual and 300 organizational members and takes no contributions from pharmaceutical companies or device manufacturers.

I am pleased today to have the opportunity to provide our perspective to CDER as you define a strategy for meeting its responsibilities and achieving its goals in the upcoming years. The Network was established nearly twenty years ago to provide people with information and services to enable them to take action on health issues affecting women and to serve as a clearinghouse for women's health information. Some of the very earliest actions of the Network were directed at the FDA, on behalf of women's right to have information about the drugs they take. Even before the Network was formally established, its founders were organizing, writing, testifying, and even demonstrating at the FDA on behalf of women's right to patient package inserts, a consumer's version of the prescription drug information available to physicians.

We strongly believe in the mission and the work of the FDA, and the need to ensure that the agency remains a strong regulator with the authority to safeguard our nation's drugs and devices. We also believe in the need to provide the agency with comment and criticism about how the center and the agency can meet the needs of consumers and patients and protect the public health.

We have never missed an opportunity to communicate to the FDA and its stakeholders the need for change at the FDA. However, we have consistently argued that efforts to reform the agency must build on, not dismantle the ability of the FDA to safeguard drug products. The Network's idea of change includes a vision of a strong, well-resourced public health regulator capable of more efficient review and approval of safe drugs and devices, more and better monitoring of safety and enforcement of FDA regulations, and greater public access to crucial health-related information.

As the Network has observed the evolution of the FDA over the past several years, we believe that our vision is currently unattainable. Indeed, the FDA admitted in its "Message to Stakeholders" that it is finding it increasingly difficult to meet its statutory obligations.

The disturbing rhetoric and debates of the past four years have created the impression that

the FDA's role in our country's economic and public health sectors is intrusive and interferes with industry's ability to expand its financial bottomline. This perception led to the passage of the FDA Modernization Act as well as other major changes in FDA regulations which we believe have compromised the ability of the Agency to carry out a central element of its core mission: minimizing the incidence of drug-related injury in men, women, and children.

As the FDA's authority has been relaxed, we fear that safety has been relaxed as well. In 1997 alone, the FDA received 251,000 spontaneous adverse events, nearly 100,000 more than in 1996. New Molecular Entities (NMEs) approved from 1993 to 1996 accounted for 30.2% of adverse event reports to the FDA. Further, several drugs in recent months have been withdrawn for safety reasons, including the diet pill combination Fen-Phen.

Patients and consumers are more, not less in danger of drug-related injury; are more, not less likely to have a television or magazine ad be the main source of information about prescription drugs; but less, not more likely to know of all the risks and benefits associated with the drugs they take. Most troubling to us is the fact that the FDA is doing less, not more monitoring and enforcement with fewer and fewer resources.

As you will hear from other panel participants this afternoon, the FDA simply cannot perform its core functions with the resources presently available to it. The FDA must fully exercise its role as a regulator and protector of the public health. The FDA must be its own strongest and most vociferous advocate for more resources. As Center Directors, you must carry this message to the Acting Commissioner and the future Commissioner and to Center staff.

Nowhere is the need for CDER to reassert its role as a regulator than direct-to-consumer advertising. Over the past decade, the Network has had many debates about DTC ads. Some in the Network argued that DTC would provide consumers with information that would not otherwise be given to them. Others argued that the FDA would not have the resources to police prescription drug advertising and subtly misleading information communicated to consumers. Since the voluntary moratorium on advertising ended in 1985, we have watched the evolution of drug advertising and we believe that our worst fears have been borne out. Drug companies have taken full advantage of the relaxed rules, which were further loosened in August of 1997. A recent survey done by IMS Health/Physicians Online discovered that spending on DTC increased 42% from 1996 to 1997, and patient requests for brand-name advertised drugs increased 59%. According to the same survey, projected DTC expenditures are expected to skyrocket to $1.3 billion in 1998, an increase of more than 50%.

The Network contested the ad based on the fact that Lilly completed no long-term studies on Evista's safety. Thankfully the FDA asked the company to revise its ads campaign. Soon after, however, Wyeth Aherst entered the fray with its own ad for Premarin. Wyeth's ads are also misleading. The Premarin ad insinuates that ongoing research on menopause suggests that HRT can help prevent Alzheimer's disease, macular degeneration, heart disease and bone loss.

The campaign hints very broadly at research being conducted, but fails to mention that many of the claims about HRT are based on retrospective studies which have reporting biases and that the largest prospectively planned clinical trial, the Women's Health Initiative will not have definitive answers for several more years.

In both cases, women have no way to get balanced information. If the FDA directs companies to revise an ad campaign or orders the ad pulled, consumer have no way of knowing that. An entire nation of magazine readers and TV viewers have seen the ads and the damage has already been done.

Although drug companies give consumers a web site and a toll-free number for obtaining additional information, these resources are also heavily influenced by pharmaceutical companies. The absence of an FDA Medguide program and less than adequate for-profit patient information leaflets which often omit critical data about adverse effects leave consumers at a loss.

Indeed, we have noted the parallel rise in DTC budgets and adverse event reports to the FDA, as stated earlier. Particularly alarming to us is the frightening evidence that drugs used exclusively by women are at the very top of the list of therapies with the most events reported -- Fosamax and Norplant.

Fosamax, a drug used to treat and prevent osteoporosis, runs DTC ads which give the impression that taking the drug will lead to a more energetic, healthy life for women, which may be the case. However, there are significant gastrointestinal problems associated with the drug and women must follow a strict schedule to avoid the adverse GI effects. The Norplant ads, like the Depo Provera ads mentioned earlier, present the attraction of easy to use birth control. Again, this may be the case for some women, but others may experience side effects (exacerbated in some cases by difficult removal) which make the method ill-suited for them.

Many, including some in the FDA, may argue that the number of DTC ads and the number of adverse events are not connected and that the greater number of adverse event reports is indicative of the FDA's efforts to put more time into safety monitoring. We disagree. As more drugs enter the market on the "fast track" and are approved with less data, consumers are put at risk. They are further put at risk when flashy ads which glamorize prescription drugs and minimize risks are run in print and on TV. The public health is further compromised to the inability of the FDA to effectively monitor DTC ads and punish companies that mislead.

The Network urges the FDA to rethink its rules regarding direct-to-consumer advertising. We believe that the balance has swung towards misleading information. We encourage the agency to revisit its earlier rule changes and begin to find ways in which strengthen standards for drug advertising.

We urge CDER to request more resources for more aggressive policing of ad content. If direct-to-consumer advertising continues, all pharmaceutical companies that participate should be made to fund an independent, consumer-run organization generously supported with enough resources to independently evaluate drugs advertised to consumers and drug claims made to those consumers. The Network, which has never taken money from drug companies, volunteers for this effort. Think of it as the consumer version of an industry-sponsored "educational" dinner or trip to Hawaii. In any event, the FDA must step up its monitoring accordingly. With the current level of resources devoted to monitoring drug advertising, this is simply impossible.

Part of the monitoring process must include a greater emphasis on public information. The public has a right to know when companies have been asked to revise or pull ads and the reasons why. Further, the Physicians Desk Reference is funded by a coalition of drug companies; consumers deserve access to their own version of the PDR, and to unbiased information about drugs. Physicians have access to unbiased information which dilutes the propaganda. We cannot think of providing consumers with anything else. The public's ability to hold drug companies accountable for the marketing misdeeds is essential in this process.

The FDA must ensure that consumers have access to an independent source of information on drugs that can match the accessibility of savvy direct-to-consumer advertising. As the FDA moves forward with its strategic plan, we call on the CDER to give the public more and better information about drugs than can fit into a 30 second sound byte.